

OPENING STATEMENT
OF DANIEL S. DUEBER, CEO, COAST IRB, LLC

In October of 2008, the Government Accountability Office, at the behest of this Committee, perpetrated an extensive fraud against my company, Coast IRB, LLC. It did so without probable cause that Coast had committed any crime. Indeed, no one at Coast has committed any crime.

It did so without involving the executive branch. It did so without satisfying any of the legal safeguards that the Department of Justice and the federal courts have in place. It acted without probable cause that a crime had been committed.

The GAO posed as a private business seeking review by my company of a medical device. It represented the medical device to be one that was substantially equivalent to a device approved for market by FDA.

In an elaborate scheme, GAO violated federal and state criminal laws (1) by falsely representing itself to be a medical device company; (2) by submitting a fake clinical trial address; (3) by submitting a fraudulent protocol for a fraudulent medical device; (4) by submitting a forged CV for a fake principal investigator; (5) by falsely representing the medical device to be substantially equivalent to a device approved by FDA for market; (6) by submitting a fraudulent FDA 510(k) number for the device; (7) by submitting a fraudulent Federal Wide Assurance number; and (8) by forging a Commonwealth of Virginia medical license and license numbers for its supposed principal investigator. GAO also engaged in extensive verbal and email correspondence with Coast IRB in furtherance of the fraud. The fraud would have persisted to this day had I not discovered it and had Coast not terminated the clinical trial. Had I not discovered it following receipt of this Committee's request for documents, I am confident Coast would have discovered it before its next scheduled review of the trial.

Mr. Chairman, it is the exclusive duty and province of the executive branch of this government to engage in law enforcement actions. By well settled precedent that branch alone may engage in clandestine stings upon probable cause that a crime has been committed. Innocent citizens of this country cannot be lawfully defrauded by their government. To hold otherwise replaces the rule of law with tyranny. Mr. Chairman, what the GAO has done at the request of this Committee is unlawful.

The actions here involve mail fraud, wire fraud, forging of a Commonwealth of Virginia medical license, false presentation of license numbers and 510(k) numbers, and false holding out of people to be physicians in the Commonwealth of Virginia. Coast has notified federal and state law enforcement of these crimes. They are crimes whether committed by the GAO or anyone else in the absence of probable cause. They are crimes for which those responsible should answer. Although we have informed law enforcement that GAO is behind them, a fact never affirmatively confirmed by your committee staff to me, we have asked that the crimes be investigated and that those responsible be prosecuted.

Mr. Chairman, the question confronting me, and which I hope will occur to you, is whether this Committee and the GAO have the lawful authority to defraud an innocent party to prove a political point.

My question, Sir, is whether this Committee and the GAO are above the law.